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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/536,939

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Christophe Revirron

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08/06/2008

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EXAMINER

RAMACHANDRAN, UMAMAHESWARI

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

08/06/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/536,939	Applicant(s) REVIRON, CHRISTOPHE	
	Examiner UMAMAHESWARI RAMACHANDRAN	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 10 and 22-28 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10, 22-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/12/2008 has been entered.

The examiner notes the receipt of the amendments, Rule 130, 131 and 132 affidavits and remarks received in the office on 5/12/2008. Claim 10 has been amended. Claims 1-9, 11-21, 29 have been cancelled. Claims 10, 22-28 are pending and are being examined on the merits herein.

Response to Remarks

Applicants' arguments and declaration by Dr. Bousquet have been fully considered and found not to be persuasive. Further search and consideration necessitated the new rejections presented in this office action. Thus the office action is made non-final.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10, 22, 23, 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gensthaler (Pharmazeutische Zeitung, vol. 146, no. 7, 2001-02-15, p 35-36) in view of Scheinfeld (J of Drugs in Dermatology, Publication date 12/01/2002) and further in view of van Cauwenberge et al. (Applicants cited exhibit 4, Rule 132 declaration, 5/12/2008, Allergy, 2000, 55, 116-134).

Gensthaler teaches that Levocetirizine was effective in the treatment of patients with seasonal allergic rhinitis (p 35, para 4 lines 1-2). The reference further teaches an intended study of the long-term effect of Levocetirizine in 500 adults with persistent allergic rhinitis (p 36, lines 3-8).

The reference does not teach a method of administration in a daily dosage of about 0.0005 mg to about 2 mg per kg of body weight in treating persistent allergic rhinitis patients or the number of dosages in the intended study of persistent allergic rhinitis.

Scheinfeld teach oral levocetirizine (5 mg once daily) for 32 days was reportedly effective in the treatment of patients with seasonal and perennial allergic rhinitis and further teach that levocetirizine relieves symptoms associated with house dust mite allergy (p 2, Heading: Uses to treat allergy, para 1, last line, para 2, lines 1-3). For example, administration of 5 mg of Levocetirizine to a 20 kg patient would amount to 0.25 mg/kg of body weight, or to a 40 kg patient would amount to 0.5 mg kg of body weight which falls within the range claimed in claims 22 and 23.

It would have been obvious to one of ordinary skill in the art to administer levocetirizine in the treatment of persistent allergic rhinitis because Gensthaler teaches

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the effectiveness of the compound in seasonal allergic rhinitis and further teaches the intended clinical study of persistent allergic rhinitis with the same compound. Hence one of ordinary skill in the art would have been motivated to administer levocetirizine in the treatment of persistent allergic rhinitis to obtain similar therapeutic benefits. It is known in the prior art that patients suffering from persistent allergic rhinitis are sensitive to indoor allergens like dust mites and perennial allergic rhinitis patients are sensitive to dust mites (J Allergy Clin Immunol. V 108, 5, S147, 2001). Hence one having ordinary skill in the art would have been motivated to administer levocetirizine in the treatment of persistent allergic rhinitis because of expectation of success as Scheinfeld teach levocetirizine administration to subjects suffering from perennial rhinitis. As per Webster's dictionary (<http://www.merriam-webster.com/dictionary/perennial>) perennial is defined as 'present all seasons of the year' or 'persistent without interruption'. Hence it would have been obvious to one of ordinary skill in the art at the time of the invention to have administered levocetirizine in a method of treatment of persistent allergic rhinitis. It would have been obvious to one of ordinary skill in the art at the time of the claimed invention to administer a dose of 0.0005 mg to about 2 mg per kg of body weight per patient for the treatment of persistent allergic rhinitis because Scheinfeld teach levocetirizine administration of 5 mg dosage to subjects suffering from seasonal and perennial rhinitis. The references do not teach administration of split dosages (2-5) per day. One of ordinary skill in the art would have been motivated to adjust the dosage amount or dosages administered per day by routine experimentation as one can expect similar therapeutic benefits and safety in the administration of levocetirizine to patients

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with persistent allergy as Scheinfeld has shown the drug to be safe and therapeutically beneficial in the patients with seasonal and perennial allergy rhinitis. Optimization of the dose of the compound is not considered inventive because it is a matter of routine experimentation. Applicant's attention is directed to *In re Aller*, 220 F.2d 454,456, 105 USPQ 233,235 (CCPA 1955) which states, "where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See MPEP § 2144.05, "11. Optimization of Ranges".

The references do not teach administration of levocetirizine for a period equal to more than 3 months.

van Cauwenberge et al. teach in a method of treatment of perennial allergic rhinitis that if the symptom control with antihistamines is inadequate or if the patient presents to the physician from the start with moderate to frequent symptoms a topical steroid is recommended for long term use up to several months (p 126, Heading: Perennial Allergic Rhinitis, para 4, lines 1-5).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have administered levoceterizine for a period equal to more than 3 months in a method of treatment of persistent allergic rhinitis because of van Cauwenberge et al.'s teachings. The reference teaches long term treatment (up to several months) of perennial allergic rhinitis in case the symptom control is inadequate with antihistamine or if the patients have moderate to frequent symptoms. One having ordinary skill in the art would have been motivated to administer levoceterizine for a period equal to more than 3 months in a method of treatment of persistent allergic rhinitis to alleviate all the

symptoms of persistent allergic rhinitis if the symptoms persist longer than 3 months or if they are frequent and to effectively treat the disorder.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gensthaler (Pharmazeutische Zeitung, vol. 146, no. 7, 2001-02-15, p 35-36) in view of Scheinfeld (J of Drugs in Dermatology, Publication date 12/01/2002) and further in view of van Cauwenberge et al. (Applicants cited exhibit 4, Rule 132 declaration, 5/12/2008, Allergy, 2000, 55, 116-134) as applied to claims 10, 22, 23, 25-28 above and further in view of Salmun et al. (US 2003/0236275).

Gensthaler, Scheinfeld and van Cauwenberge et al's teachings discussed as above.

The references do not teach administration of levocetirizine in administered via inhalation, topical etc. as claimed in claim 24.

Salmun et al. teaches antihistamines such as levocetirizine, desloratadine are useful in the treatment of seasonal allergic rhinitis. The reference teaches that antihistamines can be administered by different modes such as topical, inhalation, oral etc. (p 3, para 0037).

It would have been obvious to one of ordinary skill in the art at the time of the invention to administer levocetirizine by different routes of administration in a method of treatment for persistent allergic rhinitis because of the teachings of Salmun et al. Salmun et al teaches the administration of levocetirizine to be safe and beneficial in rhinitis patients and further teach that antihistamines can be administered by different modes such as topical, inhalation, oral etc. The different mode of administration is

deemed obvious since it is within the knowledge of the skilled pharmacologist and represents conventional modes of administration.

Response to Arguments

Applicants' arguments and declaration by Dr. Bousquet have been fully considered and found not to be persuasive. Applicants' argue that new categories of allergic rhinitis (IAR and PER) are different from SAR and PAR (perennial allergic rhinitis) and average skill in the art could not have predicted with reasonable certainty or had a reasonable expectation of success. In response, Gensthaller teaches that Levocetirizine was effective in the treatment of patients with seasonal allergic rhinitis further teaches an intended study of the long-term effect of Levocetirizine in 500 adults with persistent allergic rhinitis. Scheinfeld teach oral levocetirizine (5 mg once daily) for 32 days was reportedly effective in the treatment of patients with seasonal and perennial allergic rhinitis and further teach that levocetirizine relieves symptoms associated with house dust mite allergy. Applicants' submitted IDS document (Medical and Other News (www.pslgroup.com/dg/207766.htm), doctor's guide, October 2001) teach in the references section, Potter et al, levocetirizine in the treatment of perennial allergic rhinitis in patients sensitized to house mite, Horak et al. Effect of Levocetirizine and loratadine on symptom relief in house dust mite allergic patients exposed to allergen. The prior art document (IDS reference: J Allergy Clin Immunol. V 108, 5, S147, 2001) teach that majority of patients suffering from persistent allergic rhinitis are sensitized to mites (p S163, 3-1-3-1- Mites). The reference further teach that patients allergic to mites have symptoms all year around but with a recrudescence during the

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peak periods (p S163, 3-1-3-1- Mites) and the symptoms of patients allergic to mites are aggravated when it is humid. As per Websters' dictionary (<http://www.merriam-webster.com/dictionary/perennial>) perennial is defined as 'present all seasons of the year' or 'persistent without interruption'. Hence it would have been obvious to one of ordinary skill in the art at the time of the invention to have administered levoceterizine in a method of treatment of persistent allergic rhinitis. One having ordinary skill in the art at the time of the invention would have been aware that levocetirizine is effective in the treatment of seasonal and perennial allergic rhinitis. From the prior art (IDS reference: J Allergy Clin Immunol. V 108, 5, S147, 2001) it would have been obvious to one of ordinary skill in the art that majority of patients suffering from persistent allergic rhinitis are sensitized to mites and patients allergic to mites have symptoms all year around depending on the environmental conditions. Hence one having ordinary skill in the art would have been motivated in expectation of success that levocetirizine known in the prior art for the treatment of both perennial and seasonal allergic rhinitis would be useful in the treatment of persistent allergic rhinitis.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to UMAMAHESWARI RAMACHANDRAN whose telephone number is (571)272-9926. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616